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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/822,644	04/12/2004	Stephen R. Wilson	4451.002200/RFE	1907
23720	7590	02/26/2009		
WILLIAMS, MORGAN & AMERSON 10333 RICHMOND, SUITE 1100 HOUSTON, TX 77042			EXAMINER PURDY, KYLE A	
			ART UNIT	PAPER NUMBER
			1611	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/822,644	Applicant(s) WILSON ET AL.	
	Examiner Kyle Purdy	Art Unit 1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 December 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) 5-13 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4, 14 and 15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>1 sheet (09/08/2008)</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of Application

1. The Examiner acknowledges receipt of the amendments filed on 12/11/2008 wherein claim 1 has been amended and claims 24 and 25 have been cancelled.
2. Claims 1-4, 14 and 15 are presented for examination on the merits. Claims 5-13 stand as withdrawn. The following rejections are made.

Response to Applicants' Arguments

3. Applicants arguments filed 12/11/2008 regarding the rejection of claims 1-4, 14, 15, 24 and 25 made by the Examiner under 35 USC 112 first paragraph (enablement) have been fully considered and they are found persuasive. This rejection has been overcome by amendment.
4. Applicants arguments filed 12/11/2008 regarding the rejection of claims 1-4 and 15 made by the Examiner under 35 USC 102(b) over Fumelli et al. (Soc. Invest. Dermatology, 2000) have been fully considered and they are found persuasive. This rejection has been overcome by amendment.
5. However, as Fumelli is maintained in the rejections below, Applicants arguments will be addressed. In regards to Fumelli, Applicants assert:
 - A) Fumelli does not explicitly teach that carboxyfullerenes would be effective in treating dermatological conditions in the skin.
6. In response to A, the Examiner respectfully disagrees with Applicants assertion. Fumelli is directed to using carboxyfullerenes to protect human keratinocytes (skin cells) from UV induced apoptosis. It's taught that carboxyfullerenes reduce UV induced inhibition of keratinocytes proliferation, reduce free radical formation and interfere with the formation of the

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sunburn cell (see page 840). Moreover, carboxyfullerene exhibits strong antioxidant activity. It's taught that carboxyfullerenes could lead to new therapeutic strategies in the prevention of both skin aging (sunburn) and tumorigenesis. Thus, any person of ordinary skill would have been motivated to treat any disease of the skin such as sunburn characterized by excess intracellular free radical.

Applicants arguments filed 12/11/2008 regarding the rejection of claim 1-4, 14 and 15 made by the Examiner under 35 USC 103(a) over Fumelli in view of Hirsch et al. (US 7070810) have been fully considered and they are found persuasive. This rejection has been overcome by amendment to the claims.

7. Applicants arguments filed 12/11/2008 regarding the rejection of claims 24 and 25 made by the Examiner under 35 USC 103(a) over Fumelli in view of Fugan et al. (US 2003/0162837) have been fully considered and they are found persuasive. This rejection has been overcome by cancellation of said claims.

New Rejections, Necessitated by Amendment
Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

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1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

10. Claims 1-4 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fumelli et al. (Society for Investigative Dermatology, 2000, 115:5, 835-841; of record) in view of Dugan et al. (US 2003/0162837; of record).

11. Fumelli is drawn to carboxyfullerene (CF) compositions and their use in protecting human keratinocytes from ultraviolet (UV) induced sunburn and apoptosis via scavenging of oxygen free radicals scavenging. It is taught that UV radiation is a major source of damage to the skin because UV radiation creates oxygen free radicals which can oxidize lipids, bind DNA and possible cause cell death (see page 835, right column, 2nd paragraph). Fumelli discloses a method of administering the C3 form of CF, specifically that of e,e,e-C₆₀(COOH)₆ to normal human keratinocytes wherein the cells were pretreated with CF prior to UV exposure (see Materials and Methods section; see instant claims 1-4). Overall, it was found that CF is useful for protecting human keratinocytes from damage caused by free radical production (see page 836, left column, Figure 1). Such damage would include the formation of sunburn as well as tumors (see page 835, right column, 1st paragraph and page 840, left column, 1st paragraph; see instant claim 15).

12. Fumelli fails to specifically teach using a composition comprising between 0.01% to about 5% by weight of CF wherein the solvent medium of the fullerene composition is water.

13. Dugan is directed to CF and methods of use thereof. It is disclosed that fullerenes and derivatives thereof have potent antioxidant properties and such compounds act to reduce cell

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damage and death (see [0054]). It is disclosed that CF may be mixed with a variety of carrier materials such as water (see [0063]; see instant claim 1).

14. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Fumelli and Dugan with a reasonable expectation for success in arriving at a method of treating a dermatological condition by administering 0.01% to about 5% by weight of CF in a composition comprising water. Fumelli is discussed in detail above. Briefly, Fumelli motivates using CF for the treatment dermatological conditions. Fumelli fails to teach using a composition comprising between 0.01% to about 5% of CF wherein the carrier is water. Dugan is relied upon to show that CF is water soluble. With that said, Fumelli teaches that CF is to be used at a composition of 10 uM. This corresponds to a weight percentage of 0.8% when water is used as the solvent. Moreover, one would have been motivated to use water as solvent because it is frequently used as a delivery vehicle for topical formulations. Therefore, a method of administering between 0.01 to about 5% of CF in a water carrier is *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in absence of evidence to the contrary.

15. Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Fumelli et al. (Society for Investigative Dermatology, 2000, 115:5, 835-841; of record) in view of Dugan et al. (US 2003/0162837; of record) as applied to claims 1-4 and 15 above, and further in view of Hirsch et al. (US 7070810; of record).

16. Fumellis and Dugan fails to teach a method of administering an amphiphilic fullerene having the formula $B_b-C_n-A_a$.

17. Hirsch cures such a deficiency. Hirsch is directed to the synthesis and use of 'buckysome' carbon nanotubes for drug delivery. The compositions disclosed have the above $B_b-C_n-A_a$ (BCA) structure (see column 2, line 25). It is taught that B is to be an organic moiety with at least one polar head group and A is an organic moiety having between 8 and 24 carbons (see column 2, lines 26-35; see instant claim 14). These nanotubes may include anticancer drugs such as paclitaxel and doxorubicin as well as other therapeutic agents like ibuprofen, acetaminophen and doxycycline (see columns 11 and 12). The nanotubes can be used for the treatment of cancers which include skin cancer (see column 8, 15-25).

18. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Fumelli, Dugan and Hirsch with a reasonable expectation for success in arriving at a method of administering CF along with a BCA structure for the treatment of dermatological conditions. Fumelli is discussed above in detail. Briefly, Fumelli is directed to reducing the chance of sunburn and tumorigenesis of the skin by administering CF. Fumelli fails to include a BCA structure in their method. However, Hirsch cures this deficiency. Hirsch is directed to using BCA structures for administering drugs for the treatment of cancers which implicitly includes cancers of the skin. It would have been obvious to combine the two teaching because in doing so would provide a method of not only preventing the likelihood of tumorigenesis by administering CF but also provide a means for simultaneously treating a skin tumor by administering chemotherapeutic drug loaded BCA structures. Therefore, a method of administering CF as well as BCA structures in order to treat a dermatological

condition is *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in absence of evidence to the contrary.

Conclusion

19. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

20. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

21. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kyle A. Purdy whose telephone number is 571-270-3504. The examiner can normally be reached from 9AM to 5PM.

22. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Landau, can be reached on 571-272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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23. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

*/Kyle Purdy/
Examiner, Art Unit 1611
February 24, 2009*

*/David J Blanchard/
Primary Examiner, Art Unit 1643*